

1063278

# SECTION 1

JAN 12 2007

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## 510(K) SUMMARY

### SUBMITTED FOR:

**Company Name:** Portland Orthopaedics Limited  
**Address:** Unit 3, 44 McCauley St  
Matraville, NSW, 2036 Australia  
**Telephone:** + 61-2-9666-8444  
**Fax:** + 61-2-9666-8544

### SUBMITTED BY:

Elaine Duncan, M.S.M.E., RAC  
President, Paladin Medical, Inc.  
**Address:** Paladin Medical, Inc.  
PO Box 560  
Stillwater, MN 55082,  
United States of America  
**Telephone:** +1-715-549-6035  
**Fax:** +1-715-549-5380

**CONTACT PERSON:** Elaine Duncan

**DATE PREPARED:** October 25, 2006

**TRADE NAME:** Portland Cobalt Chrome Femoral Head

**COMMON NAME:** Metal Femoral Head Prosthesis

**DEVICE PROCODE & PANEL:** Orthopaedics 87 JDI, LWJ, LPH

**REGULATION:** CFR § 888.3358, Class II

### DESCRIPTION of the DEVICE:

The **Portland Cobalt Chrome Femoral Head** is provided as a single component. The device is manufactured from a cobalt chrome alloy and is available in various sizes. The internal bore of the femoral head is designed to taper lock (12/14) with the external male taper on a Portland Orthopaedics femoral hip stem providing articulation with a suitable acetabular module.

### INDICATIONS FOR USE:

510(k) Portland Orthopaedics, Ltd.

## **Page 2: 510(k) Summary**

The Portland Cobalt Chrome Femoral Head has the following indications for use:

- The patient should be skeletally mature.
- The patient's condition should be due to one or more of the following:
  1. Osteoarthritis.
  2. Rheumatoid arthritis.
  3. Tumor conditions involving the upper third of the femur or of the Acetabular.
  4. Ankylosing spondylitis.
  5. Psoriatic arthritis.
  6. Old osteomyelitis - with a long infection-free period and a normal WBC, ESR and C-reactive protein.
  7. Non union of femoral neck fracture or avascular necrosis of the femoral head.
  8. Post-traumatic fracture/dislocation of the hip.
  9. Revision of an unsuccessful arthrodesis with either poor positioning or pain in the hip, or where low back pain or knee pain is becoming disabling.
  10. Revision of an unsuccessful cemented or un-cemented hip replacement, providing sufficient bone stock is present.
  11. Revision of a previous unsuccessful femoral osteotomy, Girdlestone resection, cup arthroplasty or hemi arthroplasty.

## **SUBSTANTIAL EQUIVALENCE INFORMATION**

The Portland Cobalt Chrome Femoral Head described in this submission is substantially equivalent to cobalt chrome femoral heads manufactured by Biomet and Exactech, based on similarities of design, intended use, material and manufacturing methods. As demonstrated by the test results and materials information, the differences in the Portland Cobalt Chrome Femoral Head do not raise any new issues of safety and effectiveness.

## **SUMMARY of TESTING:**

Portland Orthopaedics, Ltd. has provided analytical and mechanical testing to demonstrate the substantial equivalence of and compliance to standards for the Cobalt Chrome Femoral Head.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Paladin Medical<sup>®</sup>, Inc.  
% Elaine Duncan, M.S.M.E., RAC  
President  
P.O. Box 560  
Stillwater, Minnesota 55082

JAN 12 2007

Re: K063278

Trade/Device Name: Portland Cobalt Chrome Femoral Head  
Regulation Number: 21 CFR 888.3358  
Regulation Name: Hip joint metal/polymer semi-constrained porous-coated uncemented  
prosthesis  
Regulatory Class: II  
Product Code: JDI, LPH, MEH  
Dated: October 25, 2006  
Received: October 31, 2006

Dear Ms. Duncan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

Page 2 – Ms. Elaine Duncan, M.S.M.E., RAC

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K063278

Device Name: Portland Cobalt Chrome Femoral Head

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Prescription Use X  
(Part 21 CFR 801 Subpart D)

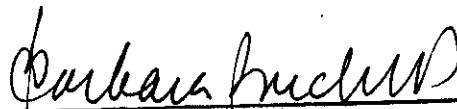
AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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(Division Sign-Off)

**Division of General, Restorative,  
and Neurological Devices**

510(k) Number K063278